Original Research Paper

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Dermatology

COMPARATIVE STUDY OF EFFICACY OF ORAL TERBINAFINE ALONE AND ORAL TERBINAFINE WITH TOPICAL 8% CICLOPIROX OLAMINE IN ONYCHOMYCOSIS IN NON HIV AND HIVPATIENTS IN KAKINADA

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ABSTRACT

AIMS: To assess the prevalence of onychomycosis among the patients attending the GGH KAKINADA.To compare the efficiency of oral terbinafine alone and oral terbinafine along with topical 8% ciclopirox olamine nail lacquer

MATERIAL & METHODS: A study was conducted on patients with onychomycosis between January 2013 to January 2014. A proforma containing detailed information on each patient was prepared according to the protocol designed for the study. Informed consent was taken from all the patients included in the study

RESULTS: Onychomycosis was the 44th commonest type of cutaneous fungal infection in the present study.The commonest age group affected was between 21-30 (45.93%) years followed by 31-40 (23.26%) years i.e. the 3rd and 4th decade.Among non HIV patients, discoloration of the nail plate, paronychia and subungual hyperkeratosis were the predominant clinical abnormalities observed.Among HIV patients, discoloration of the nail plate, onycholysis subungual hyperkeratosis were the predominant clinical abnormalities observed.Candida onychomycosis (55.64%) was the most common clinical type followed by distal lateral sub ungual onychomycosis ,(42.96%) in non HIV onychomycosis patients.In majority of HIV patients with onychomycosis the CD4 was between 401-500cells/µl. s..Terbinafine 250mg (daily dose) monotherapy showed (53.84%) mycological cure rate in HIV group and (60.87%) in Non HIV group.Combination therapy (oral terbinafine 250mg daily dose with 8% ciclopirox olamine nail lacquer) showed (66.67%) mycological cure rate in HIV group and (70.83%)in Non HIV group.Both HIV and non HIV groups ,combination therapy give high mycological cure rates than oral terbinafine monotherapy(daily dose)Onychomycosis due to candida albicans and non dermatophytes respond better to
combination therapy.Non HIV patients respond better then the HIV patients with both modalities.Combination of terbinafine daily dose monotherapy with ciclopirox olamine 8%, is effective and safe then terbinafine monotherapy.

CONCLUSIONS: combination therapy of oral terbinafine with ciclopirox olamine 8% nail lacquer is effective and safe than oral terbinafine monotherapy.

KEYWORDS : onychomycosis,terbinafine,topical 8% ciclopirox olamine

MATERIALS & METHODS:

This study has an approval of Ethics committee of Rangaraya Medical College, Kakinada.

A study was conducted on female patients with onychomycosis attending DVL OPD of Government General Hospital attached to Rangaraya Medical college, Kakinada.

Selection criteria for patients

Patients with nail abnormalities irrespective of whether they were seeking medical advice for their abnormality or not were clinically examined. All the cases diagnosed as onychomycosis on clinical examination, were subjected for mycological examination by direct microscopy (KOH) and culture.Cases confirmed by direct microscopy or culture on Sabouraud's dextrose agar or by both microscopy and culture were selected for the study.

EXCLUSION CRITERIA:

Partially treated cases of onychomycosis. Patients with liver dysfunction, diabetes mellitus, renal impairment gross anemia, pregnancy, lactation were excluded from this study.Concomitant therapy with drugs having possible interactions with terbinafine was excluded from this study

50 Non HIV onychomycosis patients who were selected for our study were randomly and equally divided into group A and group B.

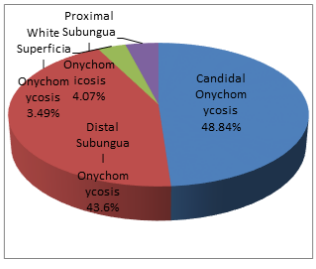
Patients in GROUP A (25) were given only oral terbinafine $_{250mg/once daily for 12 weeks}$.Patients in GROUP B (25) were given oral terbinafine$_{250mg/once daily for 12 weeks}$ along with 8%Ciclopirox Olamine nail lacquer is applied topically once daily at night.Out of 30 HIV onychomycosis 4 patients were excluded from this study because of abnormal liver enzyme levels in base line liver function tests.These 26 patients were equally divide into two groups C and D.

Patients in GROUP C (13) were given only oral terbinafine$_{250mg/once daily for 12 weeks}$

Patients in GROUP D (13) were given oral terbinafine250mg/once daily for 12 weeks along with 8%Ciclopirox Olamine nail lacquer is applied topically once daily at night.

Clinical Evolution:

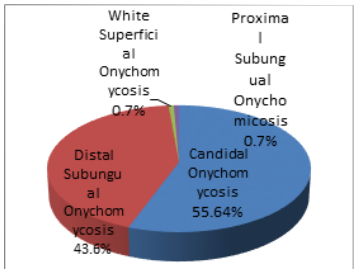
The patients were evaluted at 4 weekly intervals till 16 weeks and then 24 and 36 weeks.During these visits they were assessed for growth of a normal and healthy appearing nail plate and asked for any adverse effects of drug.In addition microscopic examination in SDA was done 16 and 36 weeks.A liver function tests was done at the base line and 1-month from the start of therapy.Clinical cure was defined as replacement of greater than of 70% of the mycotic nail bed and plate by normal and healthy appearing nail bed and plate. Mycological cure defined as negative microscopy under KOH examination and a negative culture in SDA at the end of the follow up period. At the end of the study, the result were compile, tabulated and analyzed using suitable statistical tools.



RESULTS:

The prevalence of onychomycosis in this hospital based study was 0.7%.Onychomycosis was the 44th commonest type of cutaneous fungal infection in the present study.The commonest age group affected was between 21-30 (45.93%) years followed by 31-40 (23.26%) years i.e. the 3rd and 4th decade.In both HIV (77.33%) and non HIV (85.21%)patients with onychomycosis,The lesions were asymptomatic in a majority .Among non HIV patients, discoloration of the nail plate, paronychia and subungual hyperkeratosis were the predominant clinical abnormalities observed.Among HIV patients, discoloration of the nail plate, onycholysis subungual hyperkeratosis were the predominant clinical abnormalities observed.Candida

onychomycosis (55.64%) was the most common clinical type followed by distal lateral sub ungual onychomycosis ,(42.96%) in non HIV onychomycosis patients.Distal lateral subungual onychomycosis (46.66%) was the most common type followed by proximal subungual onychomycosis (20%) in HIV onychomycosis patients.



n majority of HIV patients with onychomycosis the CD4 was between 401-500cells/µl.

Combination therapy (oral terbinafine 250mg daily dose with 8% ciclopirox olamine nail lacquer) showed (66.67%) mycological cure rate in HIV group and (70.83%)in Non HIV group.Both HIV and non HIV groups ,combination therapy give high mycological cure rates than oral terbinafine monotherapy(daily dose).Onychomycosis due to candida albicans and non dermatophytes respond better to combination therapy.Non HIV patients respond better then the HIV patients with both modalities.Combination of terbinafine daily dose monotherapy with ciclopirox olamine 8%, is effective and safe then terbinafine monotherapy

Weeks of follow up	No. of patients showing clinical cure		No. of patients showing mycological cure	
	Group A (Oral Terbinafine)	Group B (Oral Terbinafine + 8%Ciclopirox Olamine)	Group A (Oral Terbinafine)	Group B (Oral Terbinafine + 8%Ciclopirox Olamine)
Week 4	-	-	-	-
Week 8	-	-	-	-
Week 12	-	-	-	-
Week 16	1	2	2	3
Week 24	3	4	-	-
Week 36	6	6	7	8

EVALUATION SCHEDULE OF NON HIV PATIENT

Weeks of follow up	No. of patients showing clinical cure		No. of patients showing mycological cure	
	Group C (Oral Terbinafine)	Group D (Oral Terbinafine + 8%Ciclopirox Olamine)	Group C (Oral Terbinafine)	Group D (Oral Terbinafine + 8%Ciclopirox Olamine)
Week 4	-	-	-	-
Week 8	-	-	-	-
Week 12	-	-	-	-
Week 16	2	2	3	4
Week 24	6	6	-	-
Week 36	12	14	14	17

EVALUATION SCHEDULE OF HIV PATIENT

DISCUSSION:

Out of a total of 24,622 patients, who attended the Department of DVL, 401 patients had nail abnormalities. . 172 mycologically confirmed cases out of these 262 clincally suspected cases of onychomycosis, formed the study population of this study. 30 out of 172 patients were HIV positive. In the present series, majority (52.33%) of the patients were from urban areas .This is in consistant with Rigopoulos [1]et al., study which says that residence in urban areas. The commonest age group affected in the present series was between 21-30 years (45.93%) followed by 31-40 years (23.26%). A similar high incidence among 21-30 years age group was reported by Ramesh, et al.2 Among 142 non HIV patients, discolouration of the nail plate was seen in all 142 non HIV patients (100%) cases.Paronychia was seen in 75 cases (52.82%) , Subungual hyperkeratosis and onycholysis were observed in 42.25% and 23.94% respectively. paronychia was commonly seen in candidal onychomycosis..This is almost in consistant with the study done by Ramesh, et al.,[2] in which subungual hyperkeratosis (95.5%) and discoloration of the nail plate (100%), were the most common clinical signs, the presence of which should arouse a clinical suspicion of onychomycosis. Among 30 hiv patients discoloration of nail plate was seen in all 30 (100%) patients. onycholysis, subungual hyperkeratosis, distraction of nail plate and paronychia were observed in 60%,50%,40% and 16.67%, respectively. Among 142 non HIV patients Candidal onychomycosis 55.64% was the predominant clinical type observed. It was more frequently seen in those whose occupation mainly involved wet work (83.33%). Distal subungual onychomycosis (42.96%) was the second commonest type, seen mainly among those whose occupation required increased physical activity (57.97%). Higher risk of exposure to trauma in this group might be a predisposing factor. Ramesh, V. et al., [2] (1982) from India, Bokhari M.A.3 et al., (1999) from Pakistan reported distal subungal onychomycosis as the commonest clinical type in their respective studies. The predominance of candida onychomycosis in this study could probably be due to the wet working environment associated with most of the patients like housewives etc. as well as the local climate and environmental factors prevalent in this part of the country.

Among 30 HIV patients distal lateral subungual onychomycosis 10 (46.66%) was the predominant clinical type observed. It was more frequently seen in those whose occupation mainly associated with increased physical activity (70%). Proximal subungual onychomycosis 6 (20.00%) was the second commonest type, followed by, proximal subungual onychomycosis 5(16.67%) and candidial onychomycosis 5(16.67%) respectively. Higher risk of exposure to trauma in this group might be a predisposing factor. A K gupta et al[14], (1999)reported , distal lateral subungual onychomycosis type more common in HIV patients, followed by proximal sub ungual onychomycosis,white superficial onychomycosis Avner *et al*[5] [2005] studied the effectiveness of the combination of oral terbinafine and topical ciclopirox in comparison to oral terbinafine for the treatment of onychomycosis and concluded that combination therapy of oral terbinafine and ciclopirox nail lacquer is a safer and more effective treatment for onychomycosis than terbinafine alone, particularly in younger patients and for a shorter duration of onychomycosis

efficacy and is more cost-effective than terbinafine alone.

In our present study in both HIV(66.667%) and non HIV(70.83%) groups combination therapy give high mycological cure rates than oral terbinafine monotherapy.

In our present study Terbinafine 250mg (daily dose) monotherapy showed (53.84%) mycological cure rate in HIV group and (60.87 %)in Non HIV group

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Combination therapy (oral terbinafine 250mg daily dose with 8% ciclopirox olamine nail lacquer) showed (66.67%) mycological cure rate in HIV groups and(70.83%) in non HIV groups .

Both HIV(66.67%) and non HIV(70.83%) groups ,combination therapy give high mycological cure rate than oral terbinafine monotherapy(daily dose) Onychomycosis due to candida albicans and non dermatophytes respond better to Combination (oral terbinafine 250mg daily dose with 8% ciclopirox olamine nail lacquer) therapy.

Non HIV patients respond better then the HIV patients with both modalities of therapy.Combination of oral terbinafine with ciclopirox olamine 8% nail lacquer, is effective and safe then terbinafine monotherapy.

ACKNOWLEDGEMENTS: None

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